

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 5 and 6 are pending. Claims 1-4 and 7 have been withdrawn from consideration as being drawn to a non-elected invention. No new matter is added.

It is submitted that these claims are patentably distinct from the prior art, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. 35 U.S.C. §112 REJECTION

Claims 5 and 6 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was allegedly not described in the specification in such a way as to reasonably convey that at the time the application was filed, the inventors had possession of the invention. The Applicants respectfully disagree.

It is submitted that the present application provides an adequate written description of the claimed invention; thus, the following traverse is offered.

The lead case on the written description requirement is *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1970). The application of that case by the Federal Circuit is the state of the law on the issue. According to *Edwards*, the function of the written description requirement is to:

[E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by

him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

(*Id.* at 1351-52).

Thus, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by a skilled artisan. Applying the law to the instant facts, it is clear possession did exist at the time of filing.

Claims 5-6 are drawn to a pharmaceutical acceptable inhibitor of PHGPx. The Office Action states that the “Claims 5 and 6 claim compounds that are not disclosed in the body of the specification. Lack of disclosure of the identity of the compounds by means of elements such as structure which properly identify compounds and which instead are claimed by functional features, is not sufficient description to show possession of the compounds at time of filing.” (*Office Action*, at 2). Applicants assert that the skilled artisan could readily carry out the invention by following the methodology disclosed in the specification. One skilled in the art would be fully capable of identifying, obtaining, and utilizing pharmaceutical acceptable inhibitors of PHGPx.

Indeed, in addition to providing the general techniques for obtaining the claimed product, the application contains working Examples that obtained the claimed product.

Accordingly, contrary to the Office Action, there is indeed a written description of the claimed invention. Reconsideration and withdrawal of the Section 112, written description, rejection is respectfully requested.

III 35 U.S.C. § 102 REJECTION

Claims 5 and 6 were also rejected under 35 USC 102(b) as allegedly being anticipated by Maiorino et al. [*Archiv. Biochem. Biophys.* **251**, 600-605 (1986)] (“Maiorino”). The rejection is respectfully traversed.

Claims 5 is directed, *inter alia*, a pharmaceutical acceptable inhibitor of PHGPx obtained by the method of claim 1. Claim 1 recites “A method of screening for inhibitors of phospholipid hydroperoxide glutathione peroxides . . . comprising . . . selecting a pharmaceutically acceptable inhibitor which, by specifically blocking PHGPx, reversible suppresses male fertility. More specifically, Maiorino, fails to disclose, *inter alia*, pharmaceutical acceptable inhibitor of PHGPx that reversible suppresses male fertility. Although, Maiorino purports to have inhibited “phospholipid hydroperoxide glutathione peroxides” by deoxycholate and by un-saturated fatty acids, Applicants respectfully assert that deoxycholate and unsaturated fatty acids such as oleate are detergents that do not inhibit PHGPx, but inactivate PHGPx by denaturing proteins and cannot reversible suppress male fertility as claimed in claim 1. Because Maiorino does not disclose each and every element of claim 5 and dependent claim 6, the 102 rejection based on Maiorino cannot stand.

Consequently, reconsideration and withdrawal of the § 102 rejection is believed to be in order and such actions are respectfully requested.

CONCLUSION

Favorable reconsideration of the application, withdrawal of the rejections, and prompt issuance of the Notice of Allowance are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

Ronald R. Santucci
Reg. No. 28,988
(212) 588-0800